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**Please find below and/or attached an Office communication concerning this application or proceeding.**

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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 10/808,701  
Filing Date: March 25, 2004  
Appellant(s): MSIKA, PHILIPPE

\_\_\_\_\_  
ROUGET F. HENSCHÉL  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed March 8, 2010 appealing from the Office action mailed October 6, 2009.

**(1) Real Party in Interest**

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The following is a list of claims that are rejected and pending in the application:

Claims 1-24 are pending in the application. All of the claims are rejected.

**(4) Status of Amendments After Final**

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

**(5) Summary of Claimed Subject Matter**

The examiner has no comment on the summary of claimed subject matter contained in the brief.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the

Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

#### **(7) Claims Appendix**

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

#### **(8) Evidence Relied Upon**

5444091	RAPAPORT et al.	08-1995
5719129	ANDARY et al.	02-1998

Frei, V. et al., "Activation of Fibroblast metabolism in a dermal and skin equivalent model: a screening test for activity of peptides", Int'l J. of Cosmetic Science, 20, (1998) pp. 159-173.

Quelle, G., "Peptide preparation and methods for their manufacture", DE 4244418 A1, July 1, 1993, English translation (PTO 02 4395).

Flick, E., Cosmetic and Toiletry Formulations, 2nd ed., vol. 4, (1995), Noyes Publications, p. 114.

#### **(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**Claims 1-6, 8-10, 21, 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rapaport (US 5444091) in view of Frei et al (Int'l J. of Cosmetic Science) ("Frei" hereunder).**

Rapaport teaches a method of treating striae distensae lesions (stretchmarks) by topically applying to the affected skin a composition comprising alpha-hydroxy acids in the amount ranging from 2-30 % by weight, more preferably 5-20 % by weight. See Example; instant claims 1 and 9. The reference teaches lactic acid. See col. 3, lines 36 – 45; instant claim 10. The reference teaches that the composition promotes rigidity and elasticity of the skin; the

reference indicates that alpha hydroxy acids elicits a hyperplastic response in the epidermis and dermis that counters the breakdown of collagen cross linking and/or stimulates the production of materials which promote both rigidity and elasticity of the skin. See col. 4, lines 31 – 38.

While Rapaport teaches adding other ingredients including anti-oxidants and botanical extracts and to protect, prepare or mediate the action of the composition on the skin, the reference fails to teach soya protein.

Frei teaches fermented soya peptide extracted from *Lactobacillus* bacterium stimulate collagen formation and elastin synthesis when applied to skin, and increases skin firmness, elasticity, and tone. See abstract; instant claims 1-4. The peptide is said to have molecular weight of 800-1300 Daltons. See p. 161; instant claim 5-6.

It would have been obvious to one of ordinary skill in the art at the time of the present invention to modify the composition of Rapaport by incorporating soya peptide, as motivated by Frei, because Rapaport 1) teaches that stretchmarks are treated by countering the breakdown of collagen cross linking and/or stimulating production of materials which promotes the rigidity and elasticity of the skin, and 2) suggests adding additives to enhance the performance of the product; and Frei teaches that soya protein stimulates collagen formation and elastin synthesis, thereby improving firmness and elasticity of skin. The skilled artisan would have had a reasonable expectation of successfully improving the method of treating

stretchmarks since soya is expected to improve the firmness and elasticity of the skin by stimulating collagen and elastic synthesis.

**Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rapaport and Frei as applied to claims 1-6, 8-10, 21, and 22 as above, and further in view of Andary et al. (US 5719129) ("Andary")**

The combined references fail to teach the amount by which soya peptide is used in a topical composition.

Andary discloses an anti-aging cream comprising 25 % of oraposide encapsulated in liposomes, which contains soya protein in 1 % by the total weight of the oraposide liposomes. See Example 8; instant claim 7.

It would have been obvious to a skilled artisan to modify the teaching of the combined references by adding soya peptide in the amount as suggested by Andary. The skilled artisan would have been motivated to incorporate the teaching of Andary to the Rapaport/Frei prior art because all references are directed to topically treating aged skin, and Andary teaches the specific amount by which soya peptide is used in an anti-aging formulation.

**Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rapaport and Frei as applied to claims 1-6, 8-10, 21, and 22 as above, and further in view of Flick (Cosmetic and Toiletry Formulations, 1995)**

The combined references fail to teach the pH of the composition.

Flick teaches that an alpha hydroxy acid cream comprising 14.2 % of lactic acid (88%) is formulated to pH of 3.5. See p. 114.

It would have been obvious to one of ordinary skill in the art at the time of the present invention to formulate the composition of the combined references to pH of 3.5 as motivated by Flick because Rapaport teaches an alpha hydroxy acid cream wherein the alpha hydroxy acid is lactic acid used up to 30 % by weight; and Flick teaches the suitable pH of 14.2 % lactic acid (88%) composition. The skilled artisan would have had a reasonable expectation of successfully producing a stable alpha hydroxy acid cream composition that is suitable for topical application.

**Claims 12-17, 23, 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rapaport in view of Quelle (DE 4244418, English translation).**

Rapaport, as discussed above, teaches a method of treating stretchmarks by topically applying to the affected skin a composition comprising alpha-hydroxy acids in the amount ranging from 2-30 % by weight, more preferably 5-20 % by weight. See Example; instant claims 12, 15-17.

Rapaport fails to teach tripeptide consisting of the amino acids glycine, histidine, and lysine.

Quelle teaches the use of tripeptide Gly-His-Lys in cosmetic compositions to treat the skin against aging by increasing the radical scavenger effect and the stimulation of collagen synthesis of fibroblasts. See translation, p. 4, 16, Since the

reference illustrates in Application Examples 3-5 the amount of a similar but "slightly different" tripeptide preparation Gly-His-Lys used for the same purposes, it would have been obvious to a skilled artisan to use tripeptide Gly-His-Lys in this amount. See instant claim 16. The reference also teaches preparation of peptide-trace element complexes by conjugating the tripeptides with copper(II) acetate monohydrate on page 16, and the mineral substances and trace elements that are suitable for this purpose include zinc. See Claim 4, instant claims 13

It would have been obvious to one of ordinary skill in the art at the time of the present invention to modify the composition of Rapaport by incorporating the tripeptide Gly-His-Lys, as motivated by Quelle, because Rapaport 1) teaches that stretchmarks are treated by countering the breakdown of collagen cross linking and/or stimulating permanent production of materials which promotes the rigidity and elasticity of the skin, and 2) suggests adding additives to enhance the performance of the product; and Quelle teaches that the tripeptide promotes collagen synthesis and better antioxidant activity. The skilled artisan would have had a reasonable expectation of successfully enhancing the method of treating stretchmarks, since it is expected that the tripeptide would treat aging symptoms of the skin. .

**Claims 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rapaport and Quelle as applied to claims 12-17, 23, and 24 as above, and further in view of Flick.**

The combined references fail to teach the pH of the composition.

Flick teaches that an alpha hydroxy acid cream comprising 14.2 % of lactic acid (88%) is formulated to pH of 3.5. See p. 114.

It would have been obvious to one of ordinary skill in the art at the time of the present invention to formulate the composition of the combined references to pH of 3.5 as motivated by Flick because Rapaport teaches an alpha hydroxy acid cream wherein the alpha hydroxy acid is lactic acid used up to 30 % by weight; and Flick teaches the suitable pH of 14.2 % lactic acid (88%) composition. The skilled artisan would have had a reasonable expectation of successfully producing a stable alpha hydroxy acid cream composition that is suitable for topical application.

**Claims 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rapaport in view of Frei and Quelle.**

The references are discussed above. Rapaport teaches a method of topically applying alpha hydroxy acid cream to treat stretchmarks in skin.

The reference fails to teach soya peptide and tripeptide consisting of Gly-His-Lys.

Frei teaches fermented soya peptide extracted from Lactobacillus bacterium for increasing skin firmness, elasticity, and tone. See abstract; instant claims 1-4. The reference teaches the peptide a molecular weight of 800-1300 Daltons. See p. 161; instant claim 5-6.

Quelle teaches the use of tripeptide Gly-His-Lys in cosmetic compositions to treat the skin against aging and as radical scavenger (antioxidant). See abstract.

It would have been obvious to one of ordinary skill in the art at the time of the present invention to modify the method of Rapaport by adding to the alpha hydroxy acid composition soya peptide and tripeptide, as motivated by Frei and Quelle, respectively. The motivation is found in the combined teachings of the references, as 1) Rapaport teaches that stretchmarks are treated by promoting the rigidity and elasticity of the skin, and suggests adding additives to enhance the performance of the product; such as botanical extracts and antioxidants; 2) Frei teaches that soya peptide effectively improves elasticity and firmness of the skin; and 3) Quelle teaches that the tripeptide promotes collagen synthesis and better antioxidant activity. The skilled artisan would have had a reasonable expectation of successfully enhancing the method treating stretchmarks since soya peptide and tripeptide are anti-aging agents suitable for cosmetic formulations.

#### **(10) Response to Argument**

Appellant asserts the Office failed to consider the testimony filed under 37 C.F.R. Rule 132 on November 14, 2008. Examiner respectfully disagrees; the evaluation of the submitted declaration has been properly made in the subsequent Office action mailed on December 23, 2008. In it, the examiner has indicated that the declaration merely offered an opinion of the declarant/inventor on how a person of ordinary skill in the art might have interpreted the prior art references,

which did not amount to probative evidence to overcome the prima facie case of obviousness in this case. Although appellant asserts the testimony is "objective evidence", examiner views the opinion of the declarant/inventor is subjective and unpersuasive.

A. Rejection of claims 1-6, 8-10, and 21-22 as obvious over Rapaport and Frei.

i) Rapaport

Rapaport discloses a method of treating stretchmark using alpha hydroxy acids with a suggestion that alpha hydroxy acids reduces the stretchmark by (1) preserving collagen from breakdown and/or (2) stimulation of the production of interfibrillary material such as glycosaminoglycans, which promotes rigidity and elasticity of the skin.

Appellant asserts the Office erred in finding the Rapaport disclosure to teach that stretchmarks are treated by promoting the rigidity and elasticity of the skin. The declarant/inventor argues that lack of test data showing alpha hydroxy acids' efficacy in glycosaminoglycan stimulation would have led a person of ordinary skill in the art to doubt the Rapaport's disclosure. Declarant/inventor had indicated in the declaration that the Rapaport's disclosure is "speculative and unproven".

In response, examiner maintains the position that the such interpretation is based on a subjective view and does not carry probative weight in determining what a person of ordinary skill in the art would have known at the time of the

invention. It is well settled in patent law that the test of obviousness is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

In this case, Rapaport reports that a person of ordinary skill in the art knew 1) stretchmarks are caused by inflammatory processes that destroy elastic fibers and 2) previous uses of a collagen forming substance to treat stretchmarks. See col. 1, lines 33-62, citing Zheng et al. "Anatomy of Striae", British J. of Derm., 112:185-193 (1985), among others. Appellant has also acknowledged that these teachings were pertinent in stretchmark treatment art. See spec. 1, lines 18 – 36, which also cites Zheng et al., among others. Rapaport teaches topical application of an effective amount of alpha hydroxy acids (glycolic acid) has reduced striae distensae skin stretchmarks of human subjects in size and in color. See col. 2, lines 58 – 68; col. 4, lines 12-38. The prior art has provided sufficient teaching for a skilled artisan to reasonably conclude that 1) alpha hydroxy acids are effective in treating stretchmark reduction and 2) preservation of collagen, production of interfibrillary material and promoting rigidity and elasticity were highly relevant in treating stretchmarks. Therefore, regardless of the presence of test data to prove the Rapaport's suggested mechanism of the alpha hydroxy acids in glycosaminoglycan stimulation, the reference would have obviously motivated a person of ordinary skill in to use alpha hydroxy acids to treat stretchmark, just as appellant has done in this case, and further to look for other active agents, such as

soya peptide, that are effective in preserving collagen and/or stimulating collagen growth.

Declarant/inventor's assertion that a skilled artisan would have dismissed the Rapaport teaching itself is speculative and furthermore inconsistent with appellant's own disclosure, as the present invention also utilizes the same alpha hydroxy acid (lactic acid) as an active ingredient to treat stretchmarks. Therefore, examiner asserts the testimony of the Rule132 declaration amounts to a subjective opinion, not objective evidence required to overcome a prima facie case of obviousness.

ii) Frei

With respect to the Frei reference, appellant also asserts the Office has failed consider the declarant/inventor's opinion of the prior art. In the declaration, the declarant/inventor had indicated that the Frei disclosure merely shows doubts of efficacy of soya peptide in increasing skin firmness, elasticity and tone. As indicated in the previous Office action dated October 6, 2009, examiner maintains the position that a reasonable person of ordinary skill in the art would have understood that the purpose of the journal article was to teach the effect of soya peptide on a dermal and skin equivalent model so that others in the field would learn and envisage potential uses of the active ingredient and further develop it into useful articles. Appellant's assertion that the publication would have somehow deterred a skilled artisan from making the use of soya peptide is unpersuasive.

Citing MPEP 2144.02, appellant asserts the examiner had failed to provide evidentiary support to prove a scientific theory. However, a scientific theory was **not** the basis for the present rejections; the rejections are strictly based on the prior arts disclosure showing what a person of ordinary skill in the art would have known at the time of the present invention. Examiner respectfully disagrees with appellant's position that further evidentiary support would be necessary to support the obviousness rejections in this case.

B. Rejection of claim 7 as obvious over Rapaport, Frei and Andary.

Appellant asserts Andary fails to cure the alleged deficiencies of Rapaport and Frei. In response, the argument is moot as the Rapaport/Frei rejection has been properly made as discussed above.

Appellant asserts Andary's disclosure of 1 % soya peptide in an anti-aging cream does not suggest any effective amount of soya peptide for treating stretchmarks. Examiner respectfully disagrees, as both Andary and the present invention are directed to topical compositions which utilize soya peptide and its efficacy in improving aged skin condition. It would have been obvious to a skilled artisan that the disclosed amount of soya peptide in Andary would have been effective in obtaining the expected effectiveness of the soya peptide in improving the stretchmarks in the skin as appellant has done in this case.

C. Rejection of claim 11 as obvious over Rapaport, Frei and Flick.

Appellant asserts Flick fails to cure the alleged deficiencies of Rapaport and Frei. In response, the argument is moot as the Rapaport/Frei rejection has been properly made as discussed above.

Appellant also argues a person of ordinary skill in the art would have found Flick irrelevant and asserts that there is no clear basis to believe that the pH of the Flick cream would be also suitable for a cream used for treating stretchmarks. The argument is unpersuasive. Flick indicates that a skilled artisan knew the stable and safe pH range of a lactic acid topical formulation at the time of the present invention. Examiner asserts a prima facie case of obviousness has been properly established in this case, and it is appellant's burden to show reasons for a skilled artisan to believe that alpha hydroxy acids at a stable pH range somehow would not treat stretchmarks.

D. Rejection of claims 12-17 and 23-24 as obvious over Rapaport and Quelle.

Appellant asserts the Office has failed consider the declaration testimony with respect to the Rapaport/Quelle rejection. The declarant/inventor had indicated in the declaration that a person of ordinary skill in the art would not have considered stretchmark treatment relevant to aged skin treatment.

The portion of the declaration cited in support of the arguments here, however, is directed to the declarant/inventor's remarks on Rapaport and Frei, not Quelle. See Brief, p. 11-12. Nevertheless, examiner asserts that stretchmark and

aged skin treatments are considered analogous arts by one of ordinary skill in the art. See also Office action dated December 23, 2008 page 9, first paragraph.

It has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See In re Oetiker, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). As indicated the December 23, 2008 Office action, both Rapaport and Frei are directed to treating dermal atrophy by enhancing the skin firmness, elasticity and tone; Frei teaches administering soya peptides which are known to preserve collagen and/or promote collagen synthesis. Declarant/inventor's statement, "Frei is not reasonably pertinent to the problem that Rapaport seeks to solve" is inaccurate. Rapaport teaches preservation of collagen and/or promoting skin firmness and elasticity are relevant in treating stretchmarks in skin; and Frei discloses an active ingredient (i.e., soya peptide) which performs these mechanisms.

Similarly, Quelle teaches tripeptide Gly-His-Lys increases the radical scavenger effect and the stimulation of collagen synthesis of fibroblasts, and further suggests using the tripeptide conjugated with acetate in the form of a complex with zinc in a cosmetic composition. One of ordinary skill in the art would have reasonably found Rapaport and Quelle analogous arts because both references are directed to skin disorders that are known to be treated by enhancing collagen preservation and/or stimulating collagen synthesis of

fibroblasts. As indicated above, appellant has acknowledged that a person of ordinary skill in stretchmark treatment art knew at the time of the present invention 1) stretchmarks are caused by inflammatory processes that destroy elastic fibers and 2) previous uses of a collagen forming substance to treat stretchmarks. See spec. 1, lines 18 – 36. Therefore, examiner asserts Quelle is in the appellant's endeavor and reasonably pertinent to the particular problem with which the appellant was concerned.

E. Rejection of claim 18 as obvious over Rapaport, Quelle and Flick

Appellant asserts the rejection should be reversed as the rejection for claim 13, to which claim 18 depends, should be allowed. The argument is unpersuasive as the rejection for claim 13 is maintained.

F. Rejection of claims 19-20 as obvious over Rapaport and Quelle.

Appellant asserts the rejection should be reversed for the reasons noted above. In response, the arguments are unpersuasive for the reasons of record and as discussed above.

In conclusion, claims 1-24 have been properly rejected in view of the teachings of the references as discussed above. The November 14, 2008 declaration merely offers declarant/inventor's subjective opinions on how a skilled artisan might have interpreted the prior arts and fails to overcome the prima facie case of obviousness established in this case. Therefore, examiner respectfully asserts the rejections should be affirmed.

**(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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